

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

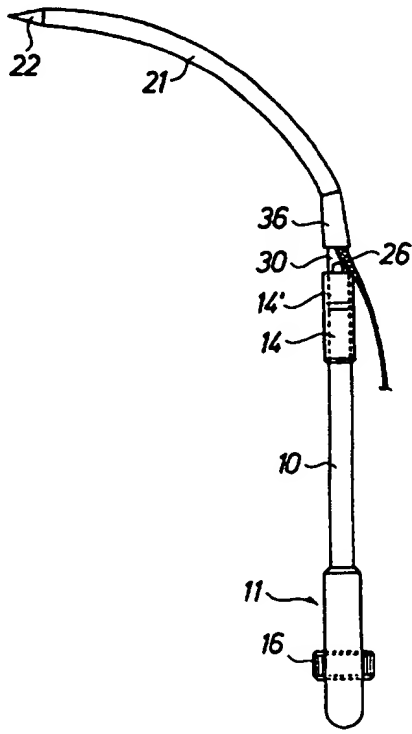
**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/04</b>	<b>A1</b>	(11) International Publication Number: <b>WO 97/13465</b> (43) International Publication Date: 17 April 1997 (17.04.97)
<p>(21) International Application Number: PCT/SE96/01269</p> <p>(22) International Filing Date: 8 October 1996 (08.10.96)</p> <p>(30) Priority Data: 9503512-7 9 October 1995 (09.10.95) SE</p> <p>(71) Applicant (for all designated States except US): MEDSCAND MEDICAL AB [SE/SE]; P.O. Box 20047, S-200 74 Malmö (SE).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): ULMSTEN, Ulf [SE/SE]; Ridvägen 18 D, S-182 35 Danderyd (SE).</p> <p>(74) Agents: STRÖM, Tore et al.; Ström &amp; Gulliksson AB, P.O. Box 4188, S-203 13 Malmö (SE).</p>	<p>(81) Designated States: AU, CA, CN, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>	
<p>(54) Title: SURGICAL INSTRUMENT FOR TREATING FEMALE URINARY INCONTINENCE</p> <p>(57) Abstract</p> <p>A surgical instrument for treating female urinary incontinence comprises a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements (21A, 21B) which can be connected one at the time with the shank at the other end thereof to form a curved end portion of the shank and are attached at one end thereof each with one end of a netting (26) which is intended to be implanted into the body and is covered by a thin plastic sheath (34).</p> 		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LJ	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

**Surgical instrument for treating female urinary  
incontinence**

5

The invention relates to a surgical instrument for treating female urinary incontinence, of the type described in PCT/SE95/00964 the content of which is incorporated herein by reference, comprising a shank having a handle at one end thereof, and two curved needle-like elements which are each attached at one end thereof to one end of a tape to be implanted into the body, and are constructed to be connected one at the time with the shank to form a curved portion at the other end thereof each element being  
15 intended to be passed into the body via the anterior (suburethral) vaginal wall and being dimensioned to extend from the inside surface of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall.

The object of the invention is to further improve the surgical instrument disclosed in said document and for this purpose the instrument of the invention has obtained the characterizing features of claim 1.  
20

The invention will be explained in more detail with reference to the accompanying drawings which disclose the surgical instrument according to the invention and wherein.  
25

FIG. 1 is a side view of the surgical instrument according to the invention,  
FIG. 2 is a plan view of the surgical instrument,  
FIG. 3 is an exploded side view of one of the needles and tape and shrinkage hose to be connected with said  
30 needle,  
FIG. 4 is a side view of the needle in FIG. 3 with the tape connected therewith,  
FIG. 5 is an enlarged fragmentary axial cross sectional view of a coupling of the instrument for connecting an exchangeable needle thereof, and  
35

FIG 6 is a side view of two needles and a tape inter-connecting said needles.

In the following description the same reference numerals have been used as in PCT/SE85/00964 for corresponding  
5 details of the instrument.

The surgical instrument comprises a cylindrical tubular shank 10 having at one end thereof a handle 11. At the other end of the shank there is a socket 14. A cylindrical shaft 15 is rotatably mounted in the shank and can be  
10 rotated manually by means of a knob 16 mounted to one end of the shaft. The other end of the shaft forms a cylindrical portion 17, FIG 5, of smaller outside diameter than the shaft, which joins a portion 18 having external threads, a smooth end portion 19 of further reduced dia-  
15 meter joining the threaded portion 18, end portion 19 forming a guide pin at said other end of the shaft. Portions 18 and 19 are received in the portion of socket 14 projecting from the shank. The surgical instrument as described so far is in agreement with the instrument disclosed in PCT/SE95/00964 except that the end portion 14' of  
20 socket 14 is flattened from opposite sides (cfr FIGS 1 and 2), so that the cross section of said end portion is non-circular.

The surgical instrument also includes an exchangeable  
25 and disposable needle 21 which at one end thereof is attached to the shank at one end of the needle and extends over substantially a quarter of a circle to the other, free end thereof in order to follow substantially the profile of the pubis between the vagina and the abdominal wall. The  
30 needle has uniform circular cross section and has a smooth, preferably polished outside surface. At the free end thereof the needle forms a point 22 by being terminated by a conical portion.

For attachment of needle 21 to shank 10 the needle  
35 forms at said one end thereof a straight portion 30 which

is cylindrical but has milled flat faces 31 over that part of said portion 30, extending from the adjacent end of the needle, which shall be received by socket portion 14'. The needle should be oriented in a predetermined rotational position in relation to the shank, and more particularly it should project at right angles to the plane of handle 11. This rotational position is secured by the non-circular shape of socket portion 14' and the end portion of the needle having the flat faces 31, which fits into socket portion 14'. The end portion of the needle having the flat faces 31 joins the body of the needle over a conical portion 32, which tapers towards a shoulder 33.

An axial blind hole extends from the end surface of the needle said hole having a threaded portion 23 and inwardly thereof a narrower, cylindrical portion 24. Guide pin 19 is dimensioned to be guidingly received by said latter portion when the threaded portion 18 for attaching needle 21 to the rest of the surgical instrument is screwed into threaded portion 23 of the blind hole by rotating shaft 15 by manual rotation of knob 16, the end surfaces of the shank and the needle being pressed against each other. Also this attachment is in agreement with that described in PCT/SE95/00964.

When the method as described in PCT/SE95/00964 is practised two needles 21A and 21B, FIG. 6 of the embodiment described shall be connected one at each end of a tape 26. According to the present invention the tape of the preferred embodiment comprises a mesh or netting forming openings of the order of 1 mm. A suitable material for the tape is PROLENE®, a knitted polypropylene mesh having a thickness of 0,7 mm manufactured by Ethicon, Inc., Somerville, New Jersey, USA. This material is approved by FDA in USA for implantation into the human body. The netting (tape) preferably has a width of approximately 10 mm and is enclosed in a thin polyethylene sheath 34 which in

flattened condition has substantially the same width as the tape although a difference in width is shown in FIG 2 in order to make the provision of the sheath more clear. The length of the netting should be approximately 400 mm. The  
5 netting and the sheath are interconnected by means of two rows 35 of stitching. The end portion of the sheath is attached to the conical portion 32 of the needle by means of a suitable strong glue, and the interconnection of the needle and sheath is covered by a shrink hose 36 of rubber  
10 which extends from the shoulder 33 over the conical portion 32 and partly over the cylindrical end portion 30 of the needle. The shrink hose is substantially flush with the surface of the needle at the shoulder. By this arrangement the netting is securely attached to the needle.

15 The purpose of sheath 34 is above all to facilitate the insertion of the netting in the manner described in PCT/SE95/00964 i e when the netting is pulled at the ends thereof from the vaginal wall to the abdominal skin and to avoid that rough edges of the netting irritate or damage  
20 the body tissues.

When the tape has been positioned in the correct position as a sling around the urethra the polyethylene sheath shall be removed, and in order to facilitate the removal the sheath should be perforated at the longitudinal center  
25 thereof as indicated by a dot-and-dash line 37 in FIG. 6, so that the two halves of the sheath can be withdrawn from the body by pulling at the respective outer ends thereof the halves being separated at the perforation under the influence of the pulling force.

30 The purpose of the polyethylene sheath is also to protect the netting during attachment to the needles and during handling before and during insertion into the body.

The longitudinal center of the tape and sheath should be indicated by a visible colour mark 38, FIG. 6 so that  
35 the surgeon readily can see when the netting is sym-

metrically located with reference to urethra during the surgery.



## CLAIMS

1. Surgical instrument for treating female urinary incontinence, comprising a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements  
5 (21) which are each attached at one end thereof to one end of a tape (26) to be implanted into the body, and are constructed to be connected one at the time with the shank to form a curved portion at the other end thereof each element being intended to be passed into the body via the  
10 anterior (suburethral) vaginal wall and being dimensioned to extend from the inside surface of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall, c h a r a c t e r i z e d in that the tape comprises a netting (26) enclosed by a thin plastic sheath (34).
- 15 2. Instrument as in claim 1 c h a r a c t e r i z e d in that the netting (26) is made of polypropylene.
3. Instrument as in claim 2 c h a r a c t e r i z e d in that the sheath (34) is made of polyethylene.
4. Instrument as in any of claims 1 to 3  
20 c h a r a c t e r i z e d in that the sheath (34) is perforated at the longitudinal center thereof.
5. Instrument as in any of claims 1 to 4 c h a r a c t e r i z e d in that the netting (26) and the sheath are interconnected by stitching ((35).
- 25 6. Instrument as in any of claims 1 to 5 c h a r a c t e r i z e d in that the needle-like element (21) comprises a non-circular end portion fitting into a non-circular socket (14') at said other end of the shank (10).
- 30 7. Instrument as in claim 6 c h a r a c t e r i z e d in that said end portion of the needle-like element (21) joins the rest of the element by a conical portion (32) tapering towards a shoulder (33) on the needle-like element.

8. Instrument as in claim 7 characterized in that the netting (26) and the sheath (34) are connected to the needle-like element (21) by gluing to said conical portion (32).

5 9. Instrument as in claim 8 characterized in that the netting (26) and the sheath (34) at the site of attachment thereof are covered by a shrink hose (36).

10 10. Instrument as in claim 9 characterized in that one end of the shrink hose (36) abuts the shoulder (33) and is substantially flush with the surface of the needle-like element at said shoulder.

15 11. Instrument as in claim 9 or 11, characterized in that the netting (26) and the sheath (34) project from the shrink hose (36) at the other end thereof.

20 12. Instrument as in any of claims 1 to 11, characterized in that a visible marking (38) is provided on the sheath (34) at the longitudinal center thereof.

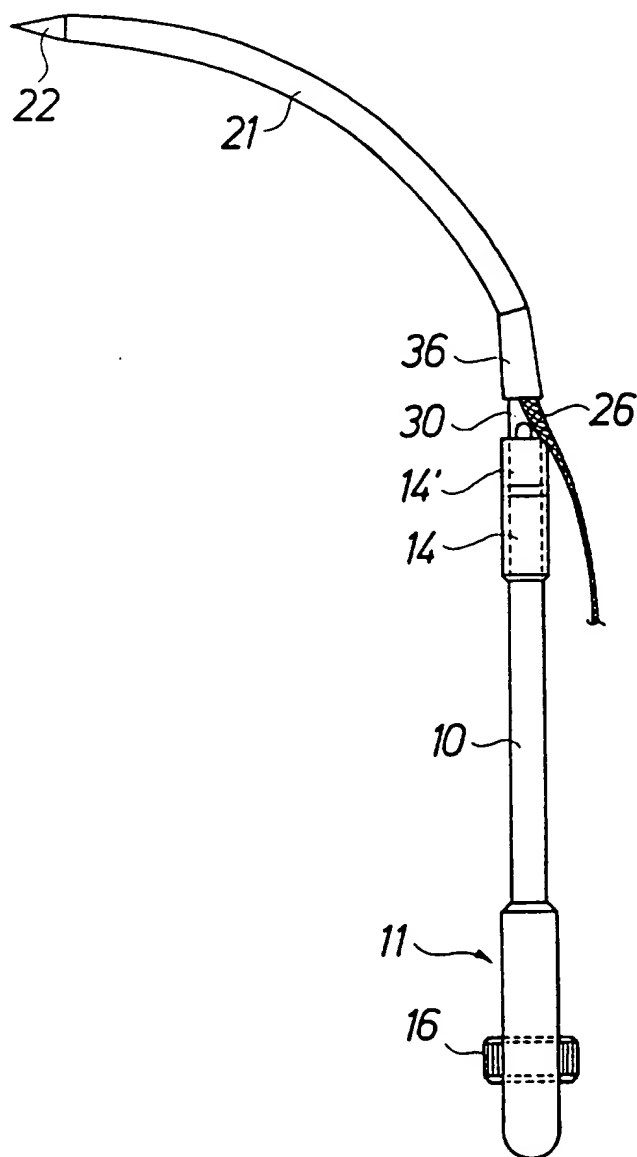


FIG. 1

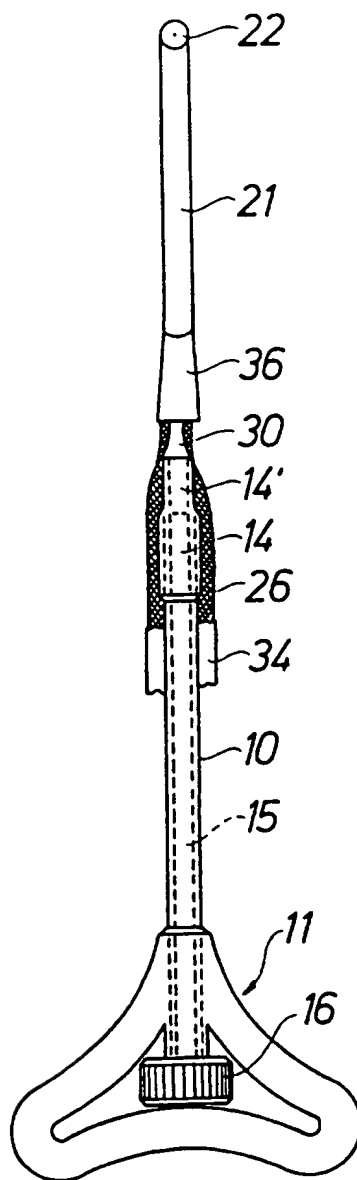


FIG. 2

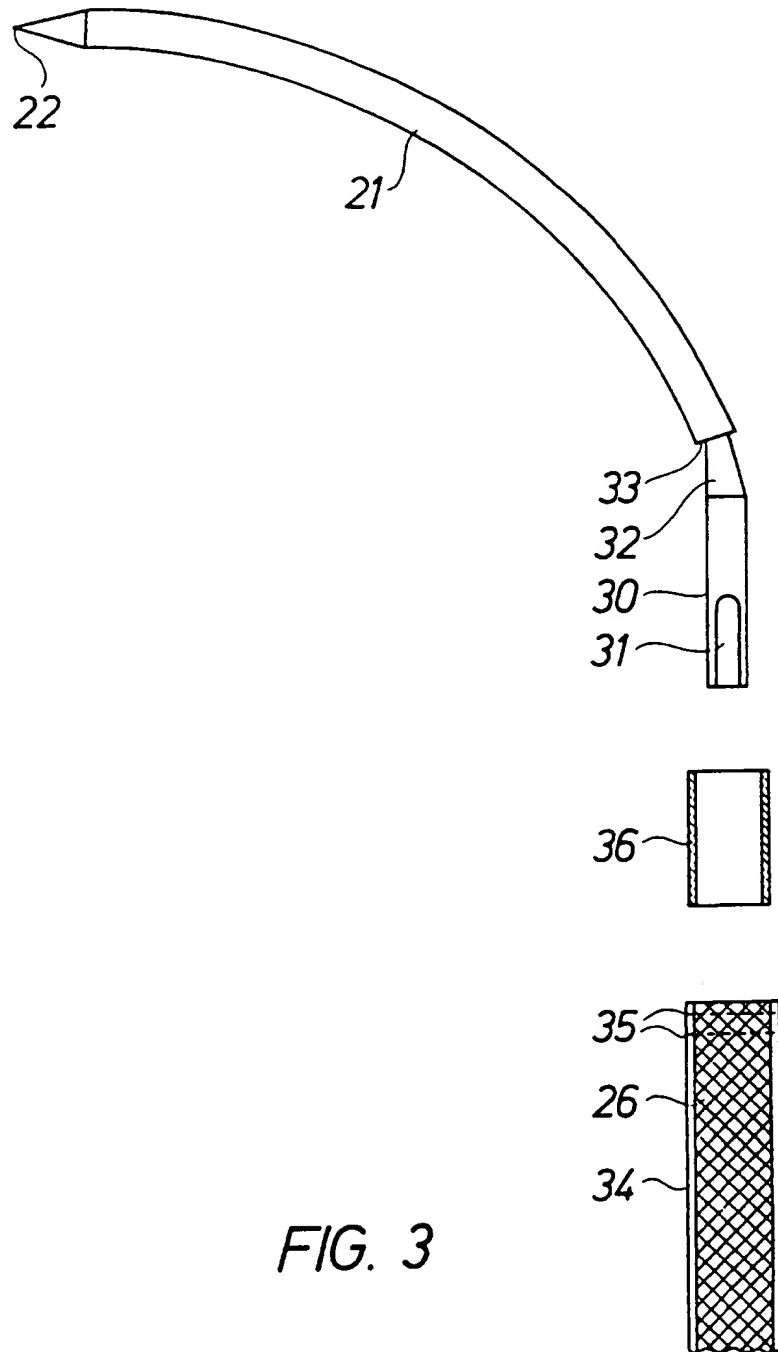
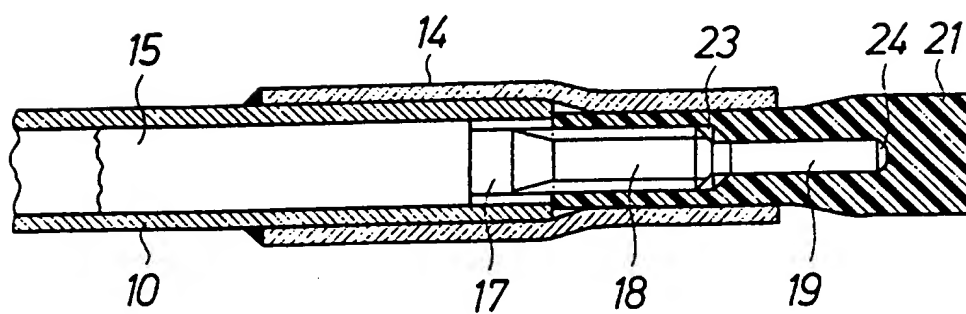
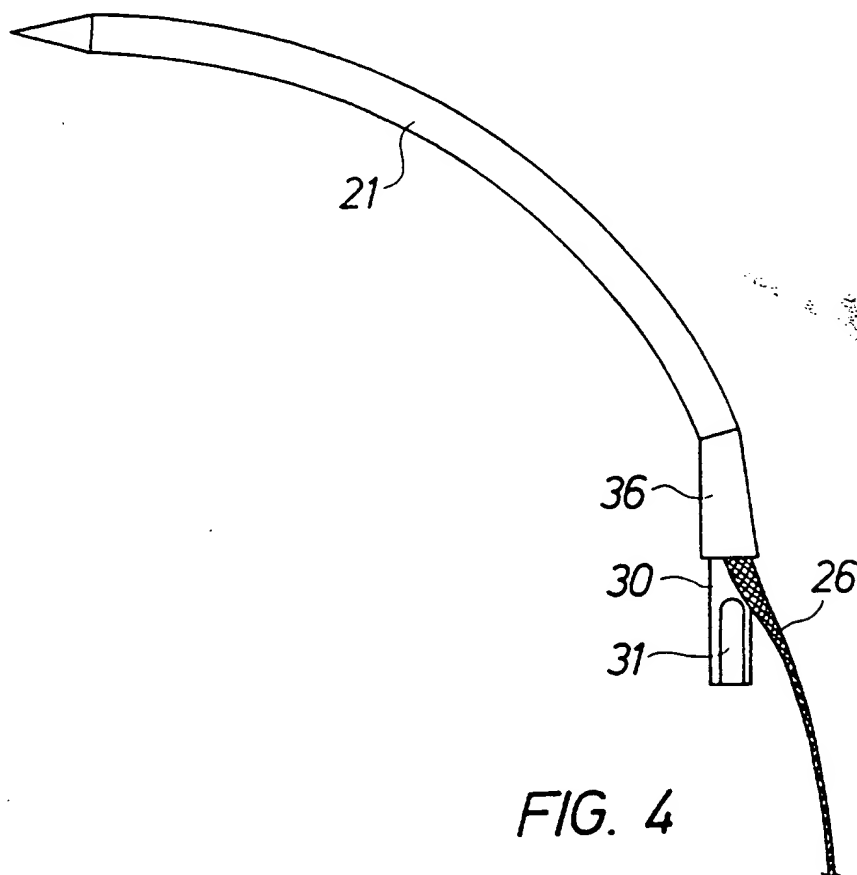
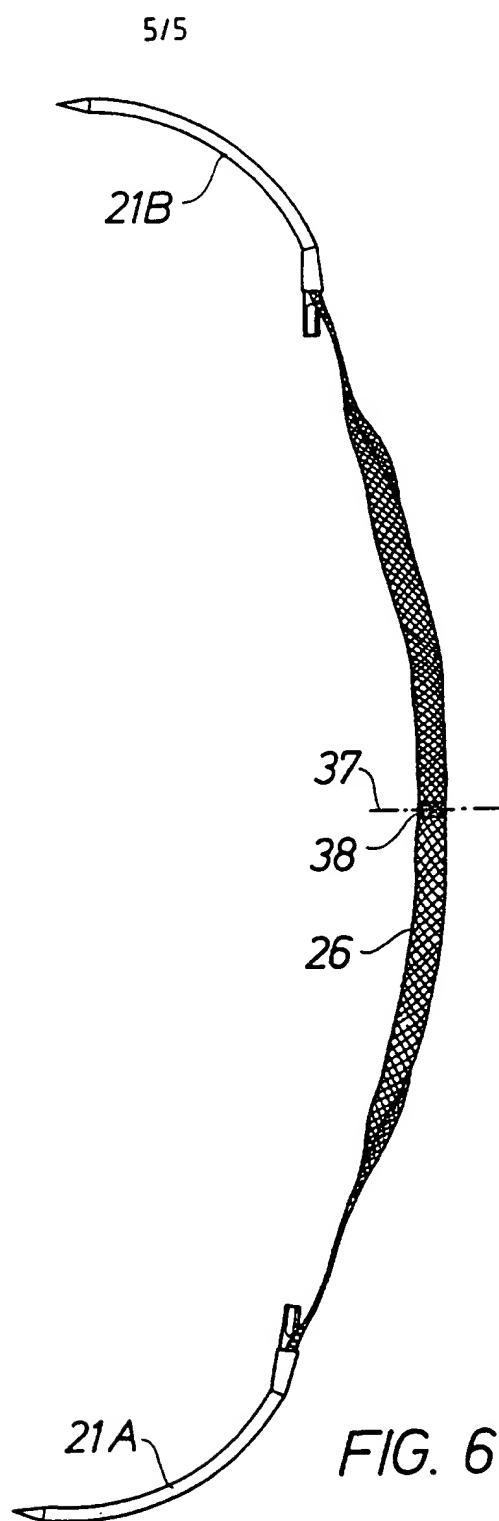


FIG. 3

4/5





**SUBSTITUTE SHEET**

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 96/01269

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
<b>IPC6: A61B 17/04</b> According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
<b>IPC6: A61B</b>		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
<b>SE,DK,FI,NO classes as above</b>		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P	SE 503271 C2 (MEDSCAND AB), 29 April 1996 (29.04.96)	
	--	
A	WO 9003766 A1 (P.E. PETROS), 19 April 1990 (19.04.90)	
	--	
A	DE 4334419 A1 (KLINIKUM DER ALBERT-LUDWIGS-UNIVERSITÄT FREIBURG.), 13 April 1995 (13.04.95)	
	--	
A	US 5403328 A (SHALLMAN,R.W.), 4 April 1995 (04.04.95)	
	-- -----	
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
5 March 1997		06.03.97
Name and mailing address of the ISA Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Anette Hall Telephone No. +46 8 782 25 00



**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

03/02/97

International application No.  
PCT/SE 96/01269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
SE-C2- 503271	29/04/96	AU-A- 3402495 SE-A- 9402872 WO-A- 9606567	22/03/96 01/03/96 07/03/96
WO-A1- 9003766	19/04/90	AT-T- 119758 AU-A- 4406489 DE-D,T- 68921762 EP-A,B- 0437481 SE-T3- 0437481 US-A- 5112344	15/04/95 01/05/90 03/08/95 24/07/91 12/05/92
DE-A1- 4334419	13/04/95	NONE	
US-A- 5403328	04/04/95	CA-A- 2094685 EP-A- 0567130	23/10/93 27/10/93